

REMARKS

The present application was filed on March 27, 2001 (claiming priority from United States Provisional Application Number 60/245,396, filed November 2, 2000) with claims 1-43. Claims 7-21, 28-32 and 39-43 have been withdrawn from consideration in response to a previous restriction requirement. Further, claims 4, 25 and 36 have been withdrawn from consideration in response to a previous species election. Claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38 are therefore currently pending in the application.

In the outstanding Office Action, the Examiner rejected claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Examiner found that the limitations of determining a hydrophobicity distribution of a protein and of shifting the hydrophobicity distribution, e.g., as recited in claims 1, 22 and 33, to be vague and indefinite.

The Examiner further rejected claims 1-3, 5 and 6 under 35 U.S.C. §101 as allegedly drawn to non-statutory subject matter. Specifically, the Examiner submitted that the present teachings do not provide a useful, concrete, and tangible result.

The Examiner rejected claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. Specifically, the Examiner submitted that the present specification does not provide enablement for a method of profiling proteins by physically changing the protein's hydrophobicity in a real environment.

The Examiner rejected claim 1 under 35 U.S.C. §102(b) as allegedly unpatentable over Bar-Or et al., Database CaPlus, DN 103:84898, Archives of Microbiology (1985), 142(1), pages 21-27 (hereinafter "Bar-Or").

The present invention relates generally to the spatial profiling of proteins using hydrophobic moments. For example, in one aspect, a method for spatially profiling proteins comprises the following steps. A hydrophobicity distribution of a protein is determined. The hydrophobicity distribution is then shifted.

FORMAL REJECTIONS

The Examiner rejected claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Examiner found vague and indefinite the limitation present in each of claims 1, 22 and 33 directed to determining a hydrophobicity distribution of a protein.

Applicant respectfully submits that the Examiner may not fully understand the limitation of determining a hydrophobicity distribution of a protein, as evidenced by the Examiner's reference to "the distribution of a protein." Office Action, page 3, 2nd full paragraph.

The present invention is directed to a hydrophobicity distribution, wherein, values of hydrophobicity are collected for amino acid residues of a protein. The hydrophobicity distribution is determined from the spatial distribution of the amino acid residues and their assigned values of hydrophobicity. See, for example, page 8, line 26 through page 9, line 3 of the specification. Thus, Applicant believes that one of ordinary skill in the art, given the present teachings, would understand the concept of a hydrophobicity distribution and would be able to assess the scope of that limitation.

The Examiner also found vague and indefinite the limitation present in each of claims 1, 22 and 33, directed to shifting the hydrophobicity distribution. Applicant respectfully points to the concept of a hydrophobicity distribution, as presented above, as being determined from the spatial distribution of amino acid residues and their assigned values of hydrophobicity. See, *Id.* The hydrophobicity distribution is shifted by subtracting the average hydrophobicity value from each assigned value of hydrophobicity. See, for example, page 9, lines 5-10 of the specification. Thus, Applicant also believes that one of ordinary skill in the art, given the present teachings, would understand the concept of shifting the hydrophobicity distribution and would be able to assess the scope of that limitation.

The Examiner rejected claims 1-3, 5 and 6 under 35 U.S.C. §101 as allegedly drawn to non-statutory subject matter. The Examiner asserted that the application discloses mathematical steps that result in a protein model having zero net hydrophobicity. Thus,

according to the Examiner, there is no useful, concrete or tangible result produced. Applicant respectfully disagrees with the Examiner's assertions.

As described above, the claims, as supported by the specification, teach determining a hydrophobicity distribution from the spatial distribution of amino acid residues and their assigned values of hydrophobicity. The hydrophobicity distribution is shifted. Applicants respectfully submit that the hydrophobicity distribution which has been shifted is a useful, concrete and tangible result. For example, the shifted hydrophobicity distribution may be used in comparing the hydrophobic moment profiles of different proteins and provide a basis for comparing hydrophobic ratios. See, for example, page 9, lines 15-19 of the specification. Thus, Applicant believes that a concrete, tangible and useful result is clearly produced.

The Examiner rejected claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. Specifically, the Examiner asserted that, while being enabling for a computer-driven computational method in a virtual environment, the specification does not reasonably provide enablement for a method of profiling proteins by physically changing the protein's hydrophobicity in a real environment. See Office Action, page 5, 2nd paragraph. Applicant respectfully disagrees with the Examiner's rejection.

It appears that the Examiner is trying to argue that the specification does not provide enablement commensurate in scope with the more broad teachings of the claims. For example, the Examiner suggested that, according to the claims, the hydrophobicity distribution of the protein may be shifted in ways, e.g., physically, which are not supported by the specification. Applicant respectfully disagrees with the Examiner's assertions on the basis that the Examiner is attempting to interpret the scope of the claims based on hypothetical and unsubstantiated embodiments which are neither taught nor suggested of in the present application nor would be practically apparent to one of ordinary skill in the art.

M.P.E.P. §2164.08 indicates that "when analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification." (emphasis added) The Examiner, in asserting that certain hypothetical embodiments are not enabled by the specification, has ignored the overall teachings of the specification and claims which do not

5 teach or suggest, e.g., physically shifting the hydrophobicity distribution of a protein. Further, applicant respectfully asserts that one of ordinary skill in the art would not contemplate derivations, such as physically shifting the hydrophobicity distribution of a protein, as it is not apparent, if at all possible, how one might go about doing that. Respectfully, the Examiner has not provided any substantiation, nor would any be apparent to one of ordinary skill in the art, for this hypothetical scenario.

Thus, Applicant submits that the present specification does enable the scope of claims to which Applicant is entitled.

PRIOR ART REJECTIONS

10 The Examiner has rejected claim 1 under 35 U.S.C. §102(b) as allegedly unpatentable over Bar-Or. Applicant respectfully disagrees with the Examiner's rejection.

Bar-Or is directed to modulating the cell-surface hydrophobicity of a cyanobacterium. Specifically, Bar-Or teaches shifting the cell-surface hydrophobicity to hydrophilicity by techniques such as mechanical shearing. See, for example, Bar-Or, Abstract. Bar-Or does not contain any teachings directed to the hydrophobicity of proteins or of shifting the hydrophobicity distribution of proteins, as recited in claim 1.

Bar-Or teaches changing cell-surface properties to make the cell surface hydrophilic. In contrast, claim 1 is directed to spatially profiling proteins. Namely, the hydrophobicity distribution of a protein is determined and shifted. Neither of these steps, nor any other techniques for profiling proteins, are disclosed in Bar-Or.

20 In view of the foregoing, the invention, as claimed in claim 1, cannot be said to be taught or suggested by Bar-Or. Accordingly, Applicant submits that all of the pending claims, i.e., claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38, are in condition for allowance and such favorable action is earnestly solicited.

25 If any outstanding issues remain, or if the Examiner has any further suggestions for expediting allowance of this application, the Examiner is invited to contact the undersigned at the telephone number indicated below.



Docket No. YOR920000779US2

The Examiner's attention to this matter is appreciated.

Respectfully submitted,

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